

Federal Register,
Vol. 59, No. 65, Tuesday, April 5, 1994
Rules and Regulations
DEPARTMENT OF ENERGY

10 CFR Part 830

RTN: 1901-AA34

Nuclear Safety Management

AGENCY: Department of Energy (DOE).

ACTION: Final rule

SUMMARY: The Department of Energy (DOE) is issuing a final rule regarding Nuclear Safety Management. This Part establishes requirements for the safe management of DOE contractor and subcontractory work at the Department's nuclear facilities. Today's rule adopts the sections that will make up the generally applicable provisions and also adopts the specific section on provisions for developing and implementing a formalized quality assurance program.

EFFECTIVE DATE: This regulation becomes effective May 5, 1994.

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I. Background

On December 9, 1991, DOE published proposed regulations adding Part 830 to Title 10 of the Code of Federal Regulations in order to establish a body of rules for the safe management of DOE nuclear facilities ("December Notice," 56 FR 64316). The December Notice addressed nine specific areas related to nuclear safety: (1) Safety Analysis Reports, (2) Unreviewed Safety Questions, (3) Quality Assurance Requirements, (4) Defect Identification, (5) Conduct of Operations, (6) Technical Safety Requirements, (7) Training, (8) Maintenance, and (9) Operational Occurrences.

DOE received written comments from 29 groups on the December Notice and held a public hearing in Germantown, Maryland, on February 25, 1992, at which five persons provided oral comments. After reviewing the written and oral comments, DOE has decided to issue a final rule

on the sections relating to the general provisions and the quality assurance requirements. DOE will issue final rules on the remaining proposed sections of Part 830 as it completes its analysis of the individual sections and the comments thereon. In order to implement the section on "Quality Assurance Requirements," It is necessary to also issue the final rules on the generally applicable provisions of part 830, §§ 830.1 through 830.7, and § 830.100, "Scope of Subpart."

Seventy-eight comments were received on the "Quality Assurance Requirements" section.

II. Response to Comments

DOE has analyzed the comments on the December Notice as they relate to: (A) Part 830, general comments, (B) the general provisions, and (C) the quality assurance requirements. Section II.A. summarizes the general comments and DOE's responses. Section II.B. summarizes comments and the Department's responses to the general provisions in §§ 830.1 through 830.7, and Section II.C. summarizes comments and the Department's responses to the quality assurance requirements in §830.120. DOE will provide its responses to comments on other proposed sections in the December Notice when it issues those sections as final rules.

A. Part 830, General Comments

B. General Provisions

C. Quality Assurance Requirements, Section 830.120

NOTE: Comments and responses are not listed here since the DOE has adopted or rejected comments in the final rule.

III. Final Rule

After considering the public comments, DOE has decided to adopt 10 CFR 830.1 through 830.7, 830.100, and 830.120 with the modifications described in the previous section and several editorial changes. A section by section description of the final rule follows.

Section 830.1 mandates that the scope of part 830 is all DOE nuclear facilities.

Section 830.2 stipulates that the activities excluded from the provisions of part 830 include activities regulated by the Nuclear Regulatory Commission (NRC) or NRC Agreement States, activities conducted by the Naval Nuclear Propulsion Program, and activities conducted under the Nuclear Explosives and Weapons Safety Program. The final rule has been modified to make clear that the exclusion applies to activities of the United States Enrichment Corporation to the extent that those activities have been certified by the NRC.

Section 830.3 provides the definitions of terms related to §§ 830.1 through 830.7, 830.100, and 830.120. New definitions for "DOE nuclear facilities" and "implementation plans" have been included to remove any ambiguity concerning the meaning of these terms.

Section 830.4, General Rule, indicates that no person shall prevent compliance with the provisions of the rule. In addition, it requires that contractors responsible for managing and operating the Department's nuclear facilities shall be responsible for implementing and complying with the provisions of part 830. Paragraph (c) has been included to make clear that contractors must comply with any plans, programs, or implementation plans required by a section and that, where required, they are intended to be the means by which compliance is determined. In particular, implementation plans will be used to set forth the manner in which full compliance with specific requirements will be attained.

Section 830.5 provides that part 830 shall be enforced according to the provisions of 10 CFR part 820, published in the Federal Register on August 17, 1993 (58 FR 43680).

Section 830.6 requires that records be maintained such that compliance with the provisions of part 830 can be substantiated.

Section 830.7 mandates the use of a graded approach when so indicated in a subpart. It also requires the documentation of the reasons for the selection of specific actions to be taken pursuant to the graded approach.

Section 830.100, Scope of Subpart, provides a statement of general applicability for Subpart A of part 830.

The "Quality Assurance Requirements" section, 830.120, mandates the development and implementation of a formalized quality assurance program. To ensure full compliance, DOE will review and approve contractor-proposed quality assurance programs and will evaluate contractor performance against the approved program including any modifications made or directed by DOE. Because of the clarification concerning implementation plans, DOE has decided to delete the proposed distinction between new and existing facilities. However, DOE does not expect to authorize the operation of any new facility unless a quality assurance program is approved and full compliance with § 830.120 is assured.

IV. Procedural Requirements

A. Review Under Executive Order 12866

Today's regulatory action has been determined to be a "significant regulatory action" under Executive Order 12866, "Regulatory Planning and Review," (58 FR 51735, October 4, 1993). Accordingly, today's action was subject to review under the Executive Order by the Office of Information and Regulatory Affairs (OIRA). There were no substantive changes between the draft submitted to OIRA and today's action.

The draft of today's action and any other documents submitted to OIRA for review have been made a part of the rulemaking record and are available for public review in the Department's Freedom of Information Reading Room 1000 Independence Avenue, SW., Washington, DC 20585 between the hours of 9 a.m. and 4 p.m., Monday through Friday, telephone (202) 586-6020.

B. Review Under the Regulatory Flexibility Act

This rule was reviewed under the Regulatory Flexibility Act of 1980, Public Law 96-354, which requires preparation of a regulatory flexibility analysis for any rule that is likely to have significant economic impact on a substantial number of small entities. DOE certifies that this final rule will not have a significant economic impact on a substantial number of small entities; therefore, no regulatory flexibility analysis has been prepared.

C. Review Under the Paperwork Reduction Act

No new information collection or record keeping requirements are imposed by this final rule. Information collection provisions of this rule were previously approved under OMB Control No. 1910-0300. Accordingly, no Office of Management and Budget clearance is required by the Paperwork Reduction Act of 1990 (44 U.S.C. 3501 *et seq.*) and the procedures implementing that Act, 5 CFR 13230.1 *et seq.*

D. Review Under the National Environmental Policy Act

The DOE has concluded that promulgation of this rule would not represent a major Federal action having significant impact on the human environment under the National Environmental Policy Act (NEPA) of 1959 [42 U.S.C. *et seq.* (1975)], or the Council of Environmental Quality regulations (40 CFR parts 1500-1508) and DOE guidelines (10 CFR part 1021). and, therefore, does not require an environmental impact statement or an environmental assessment pursuant to NEPA.

E. Review Under Executive Order 12612

Executive Order 12612, 52 FR 41685 (October 30, 1987) requires that regulations, rules, legislation, and any other policy actions be reviewed for any substantial direct effects on States, or the relationship between the National Government and the States, or in the distribution of power and responsibilities among various levels of Government. If there are sufficient substantial direct effects on States, or the relationship between the National Government and the States, or in the distribution of power and responsibilities among various levels of Government, the Executive Order requires preparation of a federalism assessment to be used in all decisions involved in promulgating and implementing a policy action. This final rule will not have a substantial direct effect on the institutional interests or traditional function of States.

F. Review Under Executive Order 12778

Section 2 of Executive Order 12778 instructs each agency to adhere to certain requirements in promulgating new regulations and reviewing existing regulations. and reviewing existing regulations.

These requirements, set forth in sections 2(a) and (b)(2), include eliminating drafting errors and needless ambiguity, drafting the regulations to minimize litigation, providing clear and certain legal standards for affected conduct, and promoting simplification and burden reduction. Agencies are also instructed to make every reasonable effort to ensure that the regulation specifies clearly any preemptive effect, effect on existing Federal law or regulation, and retroactive effect, describes any administrative proceedings to be available prior to judicial review and any provisions for the exhaustion of such administrative proceedings, and defines key terms. The DOE certifies that today's rule meets the requirements of section 2(a) and (b)(2) of Executive Order 12778.

List of Subjects in 10 CFR Part 830

Federal buildings and facilities, Nuclear energy, Nuclear material, Nuclear reactors, Reporting and record keeping requirements, and Safety.

Issued in Washington DC, on 29 March 1994.

Tara O'Toole.

Assistant Secretary, Environment, Safety and Health.

For the reasons set forth in the preamble, Title 10, Chapter III, of the Code of Federal Regulations is amended by adding a new part 830 as follows:

Part 830

NUCLEAR SAFETY MANAGEMENT

Sec.

§ 830.1 Scope.

§ 830.2 Exclusions

§ 830.3 Definitions.

§ 830.4 General rule.

§ 830.5 Enforcement.

§ 830.6 Records.

§ 830.7 Graded approach.

Subpart A - General Provisions

§ 830.100 Scope of subpart.

§ 830.120 Quality assurance requirements.

Subpart B - Design [Reserved]

Subpart C - Operations [Reserved]

Subpart D - Material Management [Reserved]

Authority: 42 U.S.C. 2201, and 7191

§ 830.1 Scope.

This part governs the conduct of the Department of Energy (DOE) management and operating contractors and other persons at DOE nuclear facilities.

§ 830.2 Exclusions

This part does not apply to:

- (a) Activities that are regulated through a license by the Nuclear Regulatory Commission (NRC) or a State under an Agreement with the NRC under section 1701 of the Atomic Energy Act;
- (b) Activities conducted under the authority of the Director, Naval Nuclear Propulsion Program as described in Public La 98-525; or
- (c) Activities conducted under the Nuclear Explosives and Weapons Safety Program relating the prevention of accidental or unauthorized nuclear detonations.

§ 830.3 Definitions.

(a) The following definitions apply to this part:

Administrative Controls mean provisions relating to organization and management, procedures, record keeping, assessment, and reporting necessary to ensure safe operation of a facility.

Contractor means any person under contract with the Department of Energy with responsibility to perform activities in connection with a nuclear facility.

Department or DOE means the Department of Energy.

Fissionable materials means a nuclide capable of sustaining a neutron-induced fission chain reaction (e.g., uranium-233, uranium-235, plutonium-238, plutonium-239, plutonium-241, neptunium-237, americium-241, and curium-244).

Graded Approach means a process by which the level of analysis, documentation, and actions necessary to comply with a requirement in this Part are commensurate with:

- (1) The relative importance to safety, safeguards, and security;
- (2) The magnitude of any hazard involved;
- (3) The life cycle stage of a facility;
- (4) The programmatic mission of a facility;
- (5) The particular characteristics of a facility; and
- (6) Any other relevant factor.

Hazard means a source of danger (i.e. material, energy source, or operation) with the potential to cause illness, injury, or death to personnel or damage to a facility or to the likelihood or credibility of accident scenarios or consequence mitigation).

Implementation Plan means a document prepared by a contractor that sets forth:

- (1) When and how the actions appropriate to comply with the requirements of a section of this Part, including the requirements of a plan or program required by the section, shall be taken and
- (2) What relief will be sought if a contractor cannot attain full compliance with a requirement in a reasonable manner.

Item. is an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, or support system.

Process. A series of actions that achieves an end or result.

Quality. The degree to which an item or process meets or exceeds the user's requirements and expectations.

Quality Assurance. Actions that provide confidence that quality is achieved.

Quality Assurance Program. The overall program established by an organization to implement the requirements of this Order. The Program assigns responsibilities and authorities, defines policies and requirements, and provides for the performance and assessment of work.

Reactor means, unless it is modified by words such as containment, vessel, or core, the entire nuclear reactor facility, including the housing, equipment, and associated areas devoted to the operation and maintenance of one or more reactor cores. Any apparatus that is designed or used to sustain nuclear chain reactions in a controlled manner, including critical and pulsed assemblies and research, test and power reactors, is defined as a reactor. All assemblies designed to perform subcritical experiments that could potentially reach criticality are also to be considered reactors. Critical assemblies are special nuclear devices designed and used to sustain nuclear reactions. Critical assemblies may be subject to frequent core and lattice configuration change and may be used frequently as mockups of reactor configurations.

Record means a completed document or other media that provides objective evidence of an item, service, or process.

Service means the performance of work, such as design, construction, fabrication inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.

(b) Terms defined in the Act and not defined in these rules are used consistent with the meanings given in the Act.

(c) As used in this Part, words in the singular also include the plural and words in the masculine gender also include the feminine and vice versa, as the case may require.

§ 830.4 General rule.

(a) No person shall take or cause to be taken any action inconsistent with the requirements of this Part or any program, plan, schedule, or other process established by this Part.

(b) With respect to a particular DOE nuclear facility, the contractor responsible for the design, construction, operation, or decommissioning of that facility shall be responsible for implementation of, and compliance with, the requirements of this Part.

(c) When a section of this part expressly requires a plan, program, or implementation plan, the provisions of any such plan, program, or implementation plan, as approved by DOE, shall be the basis used to determine compliance with the relevant nuclear safety requirements in the section.

§ 830.5 Enforcement.

The requirements in this Part are DOE Nuclear Safety Requirements and are subject to enforcement by all appropriate means, including the imposition of civil and criminal penalties in accordance with the provisions of Part 820 of this title.

§ 830.6 Records.

A person shall maintain complete and accurate records as necessary to substantiate its compliance with the requirements of this Part.

§ 830.7 Graded approach.

(a) Where indicated in a subpart, a graded approach shall be utilized to comply with the requirements.

(b) Whenever a graded approach is applied in meeting a DOE nuclear safety requirement, the bases for selecting an action pursuant to the graded approach shall be documented.

Subpart A - General Provisions

§ 830.100 Scope of subpart.

This subpart prescribes requirements that are generally applicable to more than one phase of the life cycle of a DOE nuclear facility.

§ 830.120 Quality assurance requirements.

(a) *General Rule.* (1) A contractor responsible for a DOE nuclear facility shall:

- (i) Conduct its work in accordance with the criteria of paragraph (c) of this section;
- (ii) Develop and submit for approval by DOE a Quality Assurance Program (QAP) for the work, and
- (iii) Implement the QAP, as approved and modified by DOE.

(b) *Quality Assurance Program*

[1] A contractor shall develop a QAP by applying the quality assurance criteria specified in paragraph (c) of this section. The criteria of paragraph (c) of this section shall be applied using a graded approach. The contractor shall use appropriate standards, whenever applicable, to develop and implement its QAP.

[2] Within 180 days after May 5, 1994, a contractor shall submit to DOE for approval a current QAP and an implementation plan.

[3] A contractor may, at any time, make changes to an approved QAP. Changes made over the previous year shall be submitted annually to DOE for review. A submittal shall identify the changes, the pages affected, the reason for the changes, and the basis for concluding that the revised QAP continues to satisfy the requirements of this section. Changes made to correct spelling, punctuation, or other editorial items do not require explanation.

[4] Implementation plans and QAPs shall be regarded as approved by DOE 90 days after submittal, unless approved or rejected by DOE at an earlier date, and shall include any modification made or directed by DOE.

(3) A contractor may, at any time, make changes to an approved QAP. Changes made over the previous year shall be submitted annually to DOE for review. A submittal shall identify the changes, the pages affected, the reason for the changes, and the basis for concluding that the revised program continues, to satisfy the requirements of this section. Changes made to correct spelling, punctuation, or other editorial items do not require explanation.

(4) Implementation plans and QAPs shall be regarded as approved by DOE 90 days after submittal, unless approved or rejected by DOE at an earlier date, and shall include any modification made or directed by DOE.

(c) *Quality Assurance Criteria.*

(1) *Management.*

- (i) *Program.* A written QAP shall be developed, implemented, and maintained. The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. The QAP shall describe the management processes, including planning, scheduling, and resource considerations.

- (ii) *Personnel Training and Qualification.* Personnel shall be trained and qualified to ensure they are capable of performing their assigned work. Personnel shall be provided continuing training to ensure that job proficiency is maintained.
- (iii) *Quality Improvement.* Processes to detect and prevent quality problems shall be established and implemented. Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected according to the importance of the problem and the work affected. Correction shall include identifying the causes of problems and working to prevent recurrence. Item characteristics, process implementation, and other quality-related information shall be reviewed and the data analyzed to identify items and processes needing improvement.
- (iv) *Documents and Records.* Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design. Records shall be specified, prepared, reviewed, approved, and maintained.

(2) *Performance.*

- (i) *Work Processes.* Work shall be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means. Items shall be identified and controlled to ensure their proper use. Items shall be identified and controlled to ensure their proper use. Items shall be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection shall be calibrated and maintained.
- (ii) *Design.* Items and processes shall be designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, shall incorporate applicable requirements and design bases. Design interfaces shall be identified and controlled. The adequacy of design products shall be verified or validated by individuals or groups other than those who performed the work. Verification and validation work shall be completed before approval and implementation of the design.
- (iii) *Procurement.* The organization shall ensure that procured items and services meet established requirements and perform as specified. Prospective suppliers shall be evaluated and selected on the basis of specified criteria. Processes to ensure that approved suppliers continue to provide acceptable items and services shall be established and implemented.
- (iv) *Inspection and Acceptance Testing.* Inspection and testing of specified items, services, and processes shall be conducted using established acceptance and performance criteria. Equipment used for inspections and tests shall be calibrated and maintained.

(3) *Assessment.*

- (i) *Management Assessment.* Management shall assess their management processes. Problems that hinder the organization from achieving its objectives shall be identified and corrected.

- (ii) *Independent Assessment.* Independent assessments shall be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. The group performing independent assessments shall have sufficient authority and freedom from the line to carry out its responsibilities. Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed.